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| 10/644,256      | 08/20/2003  | David H.A. Jones     | 2578-6077US         | 6153             |

24247 7590 02/28/2007  
TRASK BRITT  
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SALT LAKE CITY, UT 84110

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| EXAMINER |
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SCHLAPKOHL, WALTER

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| ART UNIT | PAPER NUMBER |
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1636

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 02/28/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/644,256

Applicant(s)

JONES ET AL.

Examiner

Walter Schlapkohl

Art Unit

1636

WAF

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 6-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119.**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Receipt is acknowledged of the papers filed 11/20/2006 in which claims 1 and 8 were amended. Claims 1, 6-12 and 14-20 are pending. Claims 12 and 14-20 are withdrawn. Claims 1 and 6-11 are under examination in the instant Office action.

Claims 12 and 14-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/23/2005.

Any rejection of record not recited herein is hereby withdrawn.

***Specification***

The disclosure is objected to because of the following informalities: Applicant's amendment to the specification is objected to because Applicant's change in claim to priority to include PCT International Application No. PCT/EP03/007690, PCT International Application No. PCT/EP03/50201, European Patent Application No. 02077953.4 and US Provisional Patent Application Serial No. 60/397,066 has not been granted (see below).

Appropriate correction is required.

***Priority***

Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in Europe on 7/18/2002. It is noted, however, that Applicant has not filed a certified copy of the priority application as required by 35 U.S.C. 119(b).

The foreign priority claim filed on 11/20/2006 was not entered because the foreign priority claim was not filed during the time period set forth in 37 CFR 1.55(a)(1). For original applications filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the time period is during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. For applications that have entered national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT. See 37 CFR 1.55(a)(1)(ii). If Applicant desires priority under 35 U.S.C. 119(a)-(d), (f) or 365(a) based upon a

Art Unit: 1636

prior foreign application, Applicant must file a petition for an unintentionally delayed priority claim (37 CFR 1.55(c)). The petition must be accompanied by (1) the claim (i.e., the claim required by 35 U.S.C. 119(a)-(d) and (f) and 37 CFR 1.55) for priority to the prior foreign application, unless previously submitted; (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.55(a)(1) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If Applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or

Art Unit: 1636

119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

***Oath/Declaration***

Applicant's declaration which includes a foreign priority claim and which was submitted 11/20/2006 is acknowledged. Although the new declaration identifies the foreign application for patent or inventor's certificate on which priority has been claimed, such a claim has not been made pursuant to 37 CFR 1.55, and as such is without effect.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8, and therefore dependent claims 6-7 and 9-11, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

This is a new rejection not necessitated by Applicant's amendment.

Claim 1 recites "[a] cell expressing E1A and E1B proteins of an adenovirus, said cell comprising recombinant nucleic acid encoding an IgA molecule in expressible format, wherein said

Art Unit: 1636

cell is derived from a human embryonic retinoblast cell as deposited under ECACC number 96022940 by stable transfection of said human embryonic retinoblast cell with the recombinant nucleic acid encoding the IgA molecule in expressible format" in lines 1-6 (emphasis added). Claim 1 is vague and indefinite in that the metes and bounds of a "stable" transfection are unclear. Does Applicant intend such a transfection wherein the IgA molecule in expressible format is integrated into the genome of the cell, or does Applicant intend to encompass even transient transfections wherein expression is "stable" for 3 days, 5 days or a week? Furthermore, because the nature of the stable transfection is unclear, the claim is also vague and indefinite in that the steps involved in the "deriving" of the cell are also unclear.

Similarly, claim 8 recites a cell "derived from a human embryonic retinoblast cell as deposited under ECACC number 96022940 by stable transfection" (lines 2-3). Claim 8 is vague and indefinite as explained for claim 1, above.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple

Art Unit: 1636

assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1-7 and 9-11 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-50 of copending Application No. 11/039,767 is withdrawn in view of Applicant's withdrawal of product claims in the copending application 11/039,767.

#### *Response to Arguments*

Applicant stated in the remarks filed 11/20/2006 that a terminal disclaimer had been enclosed to overcome the above provisional rejection on the ground of nonstatutory obviousness-type double patenting; however, no such terminal disclaimer has

Art Unit: 1636

been received. Nevertheless, this argument has been rendered moot by the withdrawal of the product claims in copending Application No. 11/039,767.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6-7 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Berkel et al (US Patent Application Publication US 2005/0170398 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the

Art Unit: 1636

invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection is maintained for reasons of record, but has been slightly altered in order to accommodate the inclusion of claims 6-7 and to correct the erroneous inclusion of claim 2. This modification to the rejection was not necessitated by amendment.

Van Berkel et al teach PER.C6 (human embryonic retinoblast cells comprising E1A and E1B proteins of an adenovirus) which express IgA as a result of stable transfection (see entire document, especially page 3, paragraph [0018]; as well as pages 32-33, claims 28-29, 31, 34-35, 37, 39 and 47). Regarding claim 7, the IgA can be human IgA (see page 6, paragraph [0058]). Regarding claims 9-10, Van Berkel et al teach that the cells can produce at least 20 pg IgA per day (see page 8, paragraph [0072]). Regarding claim 11, because Van Berkel et al teach the expression of an IgA molecule within a PER.C6 cell, and furthermore because the Van Berkel reference teaches that the PERC6 cells are capable of producing more than 20 pg of IgA per cell per day (see paragraph [0072]), claim 11 is also rejected as anticipated by the Van Berkel reference.

Because the Office does not have the facilities for examining and comparing the Applicant's product with the

Art Unit: 1636

products of the prior art, the burden is on the Applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product) (i.e. the cells as taught by the Van Berkel reference do not produce 40 picograms IgA/cell/day). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 1, 6-7 and 9-11 are directed to an invention not patentably distinct from claims 28-29, 31, 34-35, 37, 39 and 47 of commonly assigned Patent Application No. 11/039,767. Specifically, both claim sets encompass PER.C6 cells comprising recombinant IgA molecules as described above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 11/039,767, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the

Art Unit: 1636

assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

#### *Response to Arguments*

Applicant's change in claim to priority to include PCT International Application No. PCT/EP03/007690, PCT International Application No. PCT/EP03/50201, European Patent Application No. 02077953.4 and US Provisional Patent Application Serial No. 60/397,066 is acknowledged, as is Applicant's statement that "the entire delay between the date the claim was due under paragraph a(1) of [Rule] 55 and the date claimed was unintentional" (see page 7, top, of the Remarks filed 11/20/2006). The payment of fee pursuant to Rule 1.17(t) is also acknowledged.

Art Unit: 1636

However, C.F.R. 1.55(c) clearly indicates that such a change in priority claim can only be made by way of petition:

If a claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) is presented after the time period provided by paragraph (a) of this section, the claim may be accepted if the claim identifying the prior foreign application by specifying its application number, country (or intellectual property authority), and the day, month, and year of its filing was unintentionally delayed. A petition to accept a delayed claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) must be accompanied by:

- (1) The claim under 35 U.S.C. 119(a)-(d) or 365(a) and this section to the prior foreign application, unless previously submitted;
- (2) The surcharge set forth in § 1.17(t); and
- (3) A statement that the entire delay between the date the claim was due under paragraph (a)(1) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional

(emphasis added). Therefore, Applicant's request for a change in priority is ineffective.

### **Conclusion**

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If

Art Unit: 1636

Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative.

NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view

Art Unit: 1636

the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

February 8, 2007

  
DAVID GUZO  
PRIMARY EXAMINER